ACETIC ACID - acetic acid irrigant
Hospira, Inc.

UROLOGIC IRRIGATING FLUID FOR PATIENTS REQUIRING PROLONGED INDWELLING URETHRAL CATHETERIZATION...NOT FOR TRANSURETHRAL SURGICAL PROCEDURES.
Not For Injection By Usual Parenteral Routes
Semi-Rigid Irrigation Container
R_x only

DESCRIPTION
0.25% Acetic Acid Irrigation, USP, is a sterile, nonpyrogenic aqueous solution of Glacial Acetic Acid, USP for irrigation of the urinary bladder by the transurethral route (NOT FOR TUR). Each 100 mL contains 250 mg of Glacial Acetic Acid, in water for injection.
The solution is hypotonic, 42 mOsmol/liter (calc.), in relation to the extracellular fluid compartment of the body (280 mOsmol/liter) and has a pH of 3.1 (2.8 to 3.4).
Other than the active ingredient, acetic acid, the solution contains no bacteriostat, antimicrobial agent or added buffer and is intended only for use as a single-dose irrigation. When smaller volumes are required the unused portion should be discarded.
The solution is a urinary bladder antimicrobial, acidifying irrigant.
Glacial Acetic Acid, USP is chemically designated acetic acid ($C_2H_4O_2$) a liquid miscible with water. It has the following structural formula:
CH_3COOH
Water for Injection is chemically designated H_2O.
The semi-rigid container is fabricated from a specially formulated polyolefin. It is a copolymer of ethylene and propylene. The container requires no vapor barrier to maintain the proper drug concentration.
Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.
Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period.

CLINICAL PHARMACOLOGY
Irrigation of the urinary bladder with acetic acid solution in a concentration of 0.25% has been shown to exert an antimicrobial action against a variety of microorganisms (especially ammonia-forming bacteria) that frequently gain access to the urinary bladder in patients who require prolonged indwelling urethral catheterization. Its antimicrobial action is dependent on administration via the indwelling catheter at a sufficient rate (continuous or intermittent) to maintain an effluent pH of at least 5.0. Maintenance of low pH of bladder urine also helps reduce formation of calcium encrustations in the indwelling catheter.

INDICATIONS AND USAGE
0.25% Acetic Acid Irrigation, USP is indicated as a constant or intermittent bladder rinse to help prevent the growth and proliferation of susceptible urinary pathogens (especially ammonia-forming bacteria) in the management of patients who require prolonged placement of an indwellingurethral catheter. It also may be used for periodic irrigation of an indwelling catheter to help maintain patency by reducing the formation of calcium encrustations.

CONTRAINDICATIONS
NOT FOR INJECTION BY USUAL PARENTERAL ROUTES.
This solution is contraindicated for irrigation during transurethral surgical procedures.

WARNINGS
FOR IRRIGATION ONLY. NOT FOR INJECTION.
1. Use of this solution in patients with mucosal lesions of the urinary bladder may be harmful due to irritation of the lesions. Absorption via open lesions of the bladder mucosa may result in systemic acidosis.

2. The contents of an opened container should be used promptly to minimize the possibility of bacterial growth or pyrogen formation.

3. Discard the unused portion of irrigating solution since it contains no preservative.

4. Do not heat over 66°C (150°F).

PRECAUTIONS
If pain or hematuria should occur during irrigation, it should be discontinued and the patient re-evaluated.
Do not use unless solution is clear, seal is intact and container is undamaged. Discard unused portion.

Carcinogenesis, Mutagenesis, Impairment of Fertility:
Studies with Acetic Acid Irrigation, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Nursing Mothers:
Caution should be exercised when Acetic Acid Irrigation, USP is administered to a nursing woman.

Pregnancy:
Teratogenic Effects. Pregnancy Category C. Animal reproduction studies have not been conducted with Acetic Acid Irrigation, USP. It is also not known whether Acetic Acid Irrigation, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Acetic Acid Irrigation, USP should be given to a pregnant woman only if clearly needed.

Pediatric Usage:
The safety and effectiveness have not been established. Its limited use in pediatric patients has been inadequate to fully define proper dosage and limitations for use.

ADVERSE REACTIONS
Systemic acidosis has been reported in patients receiving urinary bladder irrigation with 0.25% acetic acid solution. Urologic pain and hematuria have been reported in patients receiving urinary bladder irrigation with 0.25% acetic acid solution.

OVERDOSAGE
Systemic absorption is unlikely unless there are open lesions of the bladder mucosa that have gone undetected. In such event, discontinue the irrigation, evaluate the patient for possible systemic acidosis, intravascular hemolysis and circulatory overload and institute appropriate countermeasures as indicated. See WARNINGS, PRECAUTIONS and ADVERSE REACTIONS.
Oral LD_{50} in mice: 5 g/kg.

DOSAGE AND ADMINISTRATION
0.25% Acetic Acid Irrigation, USP may be administered by gravity drip via an administration set connected to an indwelling urethral catheter designed for continuous or intermittent two-way flow. A disposable dispensing set should be used. A bulb or piston syringe may be used for periodic irrigation of an indwelling catheter.
For continuous or intermittent irrigation, the rate of administration will correspond roughly to the rate of urine flow and should be adjusted to maintain a urinary effluent pH of 4.5 to 5.0. Nitrazine or other pH paper may be used to monitor pH, preferably at least four times daily. Drip rate should be adjusted as necessary to maintain desired pH; increasing flow rate reduces pH value and vice versa. With continuous or intermittent irrigation, each patient will require a volume of approximately 500 to 1500 mL per 24 hours.
For periodic irrigation of an indwelling catheter to maintain patency, about 50 mL is required for each irrigation and may be administered using a bulb or piston syringe for injection and aspiration as often as desired.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. See PRECAUTIONS.

HOW SUPPLIED
0.25% Acetic Acid Irrigation, USP is supplied in single-dose irrigation containers as follows:

List	Container	Size (mL)
6143	Semi-rigid	250 & 1000

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.]

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